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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,581	09/29/2003	Yuuki Tsutsui	019941-001810US	5398

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EXAMINER	
HISSONG, BRUCE D	
ART UNIT	**PAPER NUMBER**
1646	

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12/08/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/674,581	TSUTSUI ET AL.	
	Examiner	Art Unit	
	Bruce D. Hissong, Ph.D.	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 November 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7,9,13,15,19,21-27,32,33,35,36 and 38-44* is/are pending in the application.

4a) Of the above claim(s) *21-27* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7, 9, 13, 15, 19, 32-33, 35-36, 38-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/19/2009 has been entered.

2. Claims 7, 9, 13, 15, 19, 21-27, 32-33, 35-36, and 38-44 are pending, with claims 21-27 withdrawn as non-elected subject matter. Claims 7, 9, 13, 15, 19, 32-33, 35-36, and 38-44 are the subject of this office action.

Claim Objections

1. Objection to claims 7 and 13 as reading on both a composition and a method, as set forth on page 2 of the office action mailed on 8/19/2009 and page 2 of the office action mailed on 10/16/2008, is *withdrawn* in response to Applicants' amendments to the claims to specifically recite a nasal composition.

2. Objection to claim 19, as set forth on pages 2-3 of the office action mailed on 8/19/2009, is *withdrawn* in response to Applicants' amendments to the claim to specifically recite a nasal composition comprising "a mucosal adjuvant and a vaccine antigen".

Rejections Withdrawn

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Rejection of claims 13, 15, 19, 35-36, and 38-39 under 35 USC § 102(e) as being anticipated by Tovey (US 6,361,769), as set forth on pages 6-7 of the office action mailed on 8/19/2009, is *withdrawn* in response to Applicants' arguments that Tovey does not teach a composition comprising IFN-a and a vaccine antigen in the same composition.

These arguments have been fully considered and are persuasive.

Rejections Maintained

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 7, 9, 13, 15, 19, 32-33, 35-36, and 38-39 *remain rejected* under 35 USC § 102(b) as being anticipated by Takasu (*Kurume Med. J.*, 2001, Vol. 48, p. 171-174), as set forth on pages 4-6 of the office action mailed on 8/19/2009.

The claims of the instant invention are drawn to a nasal composition for nasal mucosal administration, wherein said nasal composition comprises a mucosal adjuvant for inducing both vaccine antigen-specific antibody in blood and vaccine antigen-specific antibody secreted at the mucosal surface, wherein said nasal composition comprises a natural IFN-α as the active ingredient. The claims also are drawn to a nasal composition for mucosal administration, wherein said nasal composition comprises a

combined produce of a vaccine antigen and mucosal adjuvant, wherein the mucosal adjuvant is a natural IFN-α, and nasal compositions comprising a mucosal adjuvant and a vaccine antigen, wherein the mucosal adjuvant comprises a natural IFN-α. The claims further recite specific amounts of IFN-α, and locations for inducting of vaccine-specific antibody and specific types of antibodies.

Takasu teaches a composition comprising IFN-α and a peptide antigen derived from influenza virus (see p. 172, 2nd column - 1st paragraph of "Results"), and administration of this IFN-α/peptide composition to mice. Takasu discloses that the IFN-α is murine IFN-α produced by infecting cells with a virus, and thus the produced IFN-α could be considered a "natural" IFN-α, especially in the absence of a preferred definition in the specification. Takasu also teaches that the IFN-α was present in a concentration of 1×10^5 U.

In the response received on 11/19/2009, the Applicants argue that Takasu does not anticipate the presently claimed invention because Takasu does not teach or suggest a composition having a natural IFN-α and a vaccine together in a composition as currently claimed, and because Takasu does not teach or suggest a nasal composition, wherein the nasal composition is administered through the nose. Additionally, the Applicants assert that Takasu teaches away from the present invention because Takasu teaches osmotic pump administration of flu peptide with IFN-α being injected compared with flu peptide and IFN-α being injected, wherein the latter type of administration did not work. Finally, the Applicants argue that because Takasu does not teach nasal administration of the two components at the same time, as is currently claimed, there is simply no anticipation.

These arguments have been fully considered and are not persuasive. Regarding Applicants' assertion that Takasu does not teach a composition comprising both IFN-α and a vaccine together in a composition as currently claimed, it is noted that Takasu, on page 172, 2nd column, teaches that mice were immunized "with Flu peptide mixed with IFN-α", and therefore does teach a composition comprising both IFN-α as an adjuvant and a vaccine antigen. Although this composition taught by Takasu is not explicitly taught to be a "nasal composition" the instant specification does not teach what would differentiate a "nasal composition" from another composition, and in absence of evidence to the contrary, the composition of Takasu could be administered nasally if one of ordinary skill in the art desired to do so and could therefore be considered to be the same as a "nasal composition". Regarding Applicants' arguments that Takasu teaches away from the present invention, it is noted that Takasu, in Fig. 1, shows that injected IFN-α plus Flu peptide showed an enhanced CTL response compared to vaccine alone, and thus Takasu shows that co-administration of these agents by the same route would evoke an effective

immune response. Finally, regarding Applicants' arguments that Takasu does not meet the limitations of the present invention because it does not teach nasal administration of two components at the same time, it is noted that the claims are directed towards a composition, and are not directed towards any method of administration, which is merely an intended use of the claimed product/composition. In the instant case, claim 7 is merely drawn to a composition comprising IFN-α, wherein claims 13 and 19 recite a composition comprising IFN-α and a vaccine antigen. Because Takasu teaches a composition comprising IFN-α and a vaccine antigen, wherein this composition could be administered nasally, Takasu meets the limitations of these claims. Furthermore, because the composition of Takasu is identical to that which is claimed, it would be expected, in absence of evidence to the contrary, to be capable of inducing vaccine antigen-specific antibodies in the blood and at mucosal surfaces, including IgG antibody in the blood and IgA antibody at the mucosal surface.

2. Claims 7, 9, and 32-33 *remain rejected* under 35 USC § 102(e) as being anticipated by Tovey (US 6,361,769), as set forth on pages 6-7 of the office action mailed on 8/19/2009.

The subject matter of the instant invention is described above. Tovey teaches a composition comprising natural murine IFN-α at 4 x 10^6 IU/ml (column 6, lines 19-31), and oromucosal administration of this IFN-α (see Examples 1-3).

In the response received on 11/19/2009, the Applicants argue that Tovey does not anticipate the presently claimed invention because it does not teach or suggest a composition comprising IFN-α and a vaccine in the same composition.

These arguments have been fully considered and are not persuasive. Independent claim 7 of the present invention only requires that the composition comprise IFN-a as a mucosal adjuvant. Although the claim does recite nasal administration of this mucosal adjuvant with a vaccine antigen, this is merely an intended use of the composition. Therefore, because Tovey teaches a composition comprising IFN-a for oromucosal/nasal administration, Tovey meets the limitations of the claims. Furthermore, although Tovey does not explicitly teach stimulation of antigen-specific IgG antibodies in the blood and antigen-specific IgA antibodies on the mucosal surface, it is noted that the composition of Tovey is the same as that which is claimed, as is the intended use. In absence of evidence to the contrary, it would therefore be expected that the composition of Tovey would stimulate antigen-specific IgG antibodies in the blood and antigen-specific IgA antibodies at the mucosal surface when nasally administered with a vaccine antigen.

3. Claims 7, 9, 13, 15, 19, 32-33, 35-36, and 38-39 *remain rejected* under 35 USC § 102(e) as being anticipated by Foster *et al* ("Foster" - US 6,436,391), as set forth on pages 7-8 of the office action mailed on 8/19/2009.

The subject matter of the present invention is discussed above. Foster discloses a vaccine adjuvant comprising IFN-α (column 1, lines 57-65; see also claims 1-2). Specifically, Foster teaches an adjuvant composition comprising IFN-α_8 and/or IFN-α_{14}. Foster also teaches a composition comprising an antigen and IFN-α_8 and/or IFN-α_{14} as an adjuvant (see claims 1-4 and 6-7).

In the response received on 11/19/2009, the Applicants argue that Foster does not teach or suggest a nasal composition, as is currently claimed, wherein the nasal composition is administered through the nose. The Applicants also argue that Foster only relates to specific subtypes of IFN-α, rather than IFN-α as claimed, and there is no teaching that either IFN-α subtype will elicit both vaccine antigen-specific antibody in blood and vaccine antigen-specific antibody at the mucosal surface.

These arguments have been fully considered and are not persuasive. As stated above, Foster teaches a composition comprising IFN-α_8 and/or IFN-α_{14} and a vaccine antigen. While Foster does not explicitly call this a "nasal composition" the instant specification does not teach what would differentiate a "nasal composition" from another composition, and in absence of evidence to the contrary, the composition of Foster could be administered nasally if one of ordinary skill in the art desired to do so and could therefore be considered to be the same as a "nasal composition". Furthermore, although Foster does not specifically teach a method of administering this composition through the nose, it is noted that the claims are drawn to compositions rather than methods, and administration of this composition through the nose is merely an intended use. Regarding Applicants arguments that Foster only teaches IFN-α_8 and/or IFN-α_{14} subtypes rather than IFN-α, it is noted that these subtypes are indeed naturally occurring IFN-α polypeptides (see Peskta – cited in previous office actions) and thus Foster does in fact teach a composition comprising a "natural" IFN-α and a vaccine antigen. Because the composition of Foster does comprise a "natural" IFN-α and a vaccine antigen, it is identical to what is claimed, and because the IFN-α_8 and/or IFN-α_{14} are natural IFN-α polypeptides, the compositions of Foster would be expected to stimulate antigen-specific IgG antibody in the blood and antigen-specific IgA antibody at the mucosal surface if administered nasally.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 7, 9, 13, 15, 19, 32-33, 35-36, and 38-41 *remain rejected* under 35 USC § 103(a) as being obvious in view of the combination of Staats *et al* ("Staats" - WO00/20028) and Takasu, as set forth on pages 8-9 of the office action mailed on 8/19/2009.

The subject matter of the claims of the instant invention is discussed *supra*. Staats teaches a method of eliciting an immune response by administration of a vaccine antigen and an adjuvant (see abstract, and claim 1). Staats teaches that the vaccine antigen can be either protein or peptide antigens, including protein/peptide antigens from a number of pathogenic organisms (see p. 21, line 11 – p. 23, line 2). Staats also teaches that various cytokines can be used as adjuvants (see p. 14, line 19 – p. 15, line 2, and claims 5-6). Furthermore, Staats teaches mucosal administration of the vaccine-adjuvant combination (claim 17), and also teaches that the vaccine-adjuvant induces both systemic (claim 22) and mucosal (claim 25) immune responses. Finally, by teaching that the vaccine and adjuvant are included together as a composition, Staats teach that the vaccine antigen and the adjuvant are administered at the same time and by the same route of administration. However, Staats is silent regarding the use of IFN-α as the adjuvant for any antigen-adjuvant combination or composition.

Takasu teaches that IFN-α is a potent adjuvant for increasing the immune response to various vaccine antigens. Specifically, Takasu discloses that co-administration of IFN-α with influenza virus peptide increased the cytotoxic T lymphocyte (CTL) response to the influenza virus peptide compared to vaccination with the influenza virus peptide alone (see p. 172-174, Figures 1-3).

In the response received on 11/19/2008, the Applicants argue that the claims are not obvious in view of the combination of Staats and Takasu because Staats does not teach or suggest the use of IFN-α as claimed, and Takasu does not teach nasal administration, nor that antibodies are secreted at the gastrointestinal mucosa or in the blood as currently claimed. The Applicants also argue that Takasu teaches antigen administration via an osmotic pump and injection at IFN-α, and that there is no teaching or suggestion of a nasal composition as is currently claimed. Furthermore, the Applicants argue that Takasu teaches away from the present invention by showing that injection of IFN-α and flu peptide did not work compared to osmotic pump administration of peptide and injection of IFN-α.

These arguments have been fully considered and are not persuasive. Although Takasu does not teach nasal administration of the composition comprising IFN-α and flu peptide, it is noted that contrary to Applicants' assertion, combined administration of IFN-α and flu peptide via the same route of administration did indeed elicit an enhanced CTL response compared to flu peptide alone (Takasu – Fig. 1). Therefore, one of ordinary skill in the art would know that IFN-a can function as an effective vaccine adjuvant. Combined with Staats, which teaches mucosal administration of vaccine-adjuvant compositions wherein the adjuvant can be a cytokine, a person of ordinary skill in the art would thus be motivated to use IFN-α (as taught by Takasu) as the adjuvant component of the composition of Staats. Furthermore, because Staats teaches that such compositions stimulate both systemic (i.e. blood antibodies) and mucosal immune responses, one of ordinary skill in the art would have both the motivation, and a reasonable expectation of success, in creating a composition comprising IFN-α as a vaccine adjuvant, wherein the composition may further comprise a vaccine antigen, wherein this composition could be nasally/mucosally administered and stimulate the production of antigen-specific antibodies both in the blood and at the mucosal surfaces.

2. Claims 7, 9, 13, 15, 19, 32-33, 35-36, and 38-41 *remain rejected* under 35 USC § 103(a) as being obvious in view of the combination of Foster and Tovey, as set forth on pages 10-11 of the office action mailed on 8/19/2009.

The subject matter of the claims of the instant invention is discussed *supra*. As discussed above, Foster teaches the use of IFN-α as a vaccine adjuvant to increase B lymphocyte proliferation, and thus increase the effectiveness of vaccines (column 1, lines 52-56), and specifically recites co-administration of a vaccine with IFN-α, or alternatively, a composition comprised of IFN-α and a vaccine (column 1, lines 61-65). Foster is silent regarding mucosal administration of an IFN-α vaccine-adjuvant composition, and is also silent regarding specific amounts or doses of IFN-α.

Tovey teaches a method of stimulating host immunity by oromucosal administration of IFN-α (column 2, line 32 – column 3, line 28). Tovey discloses specific doses of IFN-α that can be oromucosally administered (column 3, line 15-20), and also teaches that IFN-α can be administered as an adjunct to other therapy (column 3, lines 21-22), and specifically mentions previous studies in which IFNs where orally administered to enhance the efficiency of vaccines (column 1, lines 61-66).

In the response received on 11/19/2009, the Applicants argue that Foster teaches that not all IFN-a subtypes work (with regards to stimulation of B cell proliferation), and thus a person of ordinary skill in the art would have no expectation of success using IFN-α without separating the molecule into various

subtypes. The Applicants also argue that Tovey teaches a method of stimulating the immune response by administering IFN-α via oromucosal contact, and there is no teaching or suggestion of a mucosal adjuvant comprising a natural IFN-α and an antigen comprising a peptide antigen.

These arguments have been fully considered and are not persuasive. Regarding Applicants arguments that Foster does not provide an expectation of success to a person of ordinary skill in the art, it is noted that Foster specifically teaches which IFN-α subtypes would be expected to stimulate B cell proliferation, and because these IFN-α are naturally occurring IFN-α polypeptides, they could be considered as "natural" IFN-α polypeptides that a person of ordinary skill in the art would be motivated to include in a vaccine composition. Regarding Applicants arguments that Tovey does not teach an antigen being present in the IFN-α composition, it is noted that Tovey teaches the use of IFN-α as a mucosal vaccine adjuvant, and Foster teaches compositions with IFN-α as a vaccine adjuvant and an antigen, and therefore the combination of Foster and Tovey provides the motivation to include a vaccine antigen in a composition comprising IFN-α as a vaccine adjuvant.

3. Claim 41 *remains rejected* under 35 USC § 103(a) as being obvious in view of either Takasu or Foster, as set forth on page 11 of the office action mailed on 8/19/2009.

The subject matter of the present invention, and the disclosures of Takasu and Foster are discussed above. Claim 41 is further drawn to the mucosal adjuvant of claim 19, wherein the ratio of IFN-α is 0.01 to 5% w/w of the composition.

In the response received on 11/19/2009, the Applicants assert that because claim 41 depends from claim 19, and claim 19 is non-obvious for reasons set forth above, claim 41 therefore cannot also be obvious.

This argument has been fully considered and is not persuasive. As set forth above, claim 19 both anticipated by and obvious in view of both Takasu and Foster, and therefore claim 41 is obvious for reasons of record set forth in the previous office action.

4. Claims 42-44 *remain rejected* under 35 USC § 103(a) as being obvious in view of the combination of Takasu and Kawashima *et al* ("Kawashima" – *Pharm. Devl. Tech.*, 2000, Vol 5(1), p. 77-85), as set forth on pages 11-12 of the office action mailed on 8/19/2009.

The subject matter of the present invention and the disclosure of Takasu are discussed above. Kawashima teaches that PGLA is a biocompatible and biodegradable carrier suitable for delivering

numerous peptides/polypeptides, and teaches that PLGA can be modified in order to create microspheres capable of adhesion to the mucosal surface.

In the response received on 11/19/2009, the Applicants argue that Kawashima has nothing at all to do with nasal administration of a vaccine as claimed, and there is no teaching or suggestion of using the composition as claimed.

These arguments have been fully considered and are not persuasive. Although Kawashima does not teach nasal administration, it does teach that PLGA is a useful agent for facilitating the delivery of peptide/polypeptide agents. Thus, because Takasu teaches that IFN-α is a useful vaccine adjuvant, one of ordinary skill in the art would have the motivation to encapsulate IFN-α within PLGA microspheres for effective delivery.

5. Claims 42-44 *remain rejected* under 35 USC § 103(a) as being obvious in view of the combination of Tovey and Kawashima *et al* ("Kawashima" – *Pharm. Devl. Tech.*, 2000, Vol 5(1), p. 77-85), as set forth on pages 11-12 of the office action mailed on 8/19/2009.

The subject matter of the present invention and the disclosure of Tovey are discussed above. Kawashima teaches that PGLA is a biocompatible and biodegradable carrier suitable for delivering numerous peptides/polypeptides, and teaches that PLGA can be modified in order to create microspheres capable of adhesion to the mucosal surface.

In the response received on 11/19/2009, the Applicants argue that Kawashima has nothing at all to do with nasal administration of a vaccine as claimed, and there is no teaching or suggestion of using the composition as claimed.

These arguments have been fully considered and are not persuasive. Although Kawashima does not teach nasal administration, it does teach that PLGA is a useful agent for facilitating the delivery of peptide/polypeptide agents. Thus, because Tovey teaches that IFN-α is a useful vaccine adjuvant for mucosal delivery, one of ordinary skill in the art would have the motivation to encapsulate IFN-α within PLGA microspheres for effective mucosal delivery.

Conclusion

No claim is allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce D. Hissong, Ph.D., whose telephone number is (571)272-3324. The examiner can normally be reached M-F from 8:30 am - 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, Ph.D., can be reached at (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Bruce D. Hissong
Art Unit 1646

/Robert Landsman/
Primary Examiner, Art Unit 1647